August 17, 2018

Dr. Todd Peterson
Peer Review Leader
Office of Science Coordination and Policy (7201M)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Submitted via the Federal eRulemaking Portal: https://www.regulations.gov/

Re: EPA Exposure and Use Assessment and Ecological and Human Health Summary for Five PBT chemicals. EPA-HQ- OPPT-2018-0314

Dear Dr. Peterson:

The American Chemistry Council (ACC)[1] is pleased to submit these comments on EPA's Exposure and Use Assessment and Ecological and Human Health Summary for Five PBT chemicals.[2,3] Section 6(h) of amended TSCA authorizes EPA to identify certain persistent, bioaccumulative, and toxic substances (PBT) for expedited action. EPA identified five substances meeting the criteria set forth in the statute, conducted use and exposure assessments on those substances, and is currently conducting a letter peer review on those assessments. The five chemicals are:

- Decabromodiphenyl ethers (DecaBDE)
- Hexachlorobutadiene (HCBD)
- Pentachlorothiophenol (PCTP)
- Phenol, isopropylated, phosphate (3:1) or PIP (3:1)
- 2,4,6-Tris(tert-butyl) phenol (2,4,6-TTBP)

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®; common sense advocacy designed to address major public policy issues; and health and environmental research and product testing. The business of chemistry is a $768 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for fourteen percent of all U.S. goods exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

[2] 83 Fed. Reg. 24305 (May 25, 2018).

[3] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under

EPA has invited public comment on the charge questions and documents considered by the peer reviewers. ACC offers the following comments to help the agency strengthen those materials.

I. Comments Regarding Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic (PBT) Chemicals

A. EPA should re-consider its proposed exposure read-across approach for PIP (3:1) and 2,4,6-TTBP (Charge Question #6).

The proposal to use a read-across approach to apply exposure data among similar chemical substances is problematic. ACC strongly urges EPA to re-consider this approach for the reasons discussed below.

According to the European Chemicals Agency (ECHA), "Read-across involves the use of relevant information from analogous substance(s) (the 'source' information) to predict properties for the 'target' substance(s) under consideration." Typically, read-across has been used in hazard characterization. The Organization of Economic Cooperation and Development (OECD) states that "[i]n principle, read-across can be used to assess physicochemical properties, toxicity, environmental fate and ecotoxicity." Use of read-across for exposure characterization beyond environmental fate is not mentioned in that OECD document and is not typically applied. The OECD Guidance on Grouping of Chemicals and the ECHA Read-Across Assessment Framework provide principles for developing a hypothesis-driven justification of why data from one substance can be used to fill the data needs for another substance for hazard assessment.

We commend the extension of this principle to the area of exposure characterization. However, EPA has not identified those characteristics that would make a surrogate chemical suitable for read-across for exposure. Physical-chemical similarity alone is not sufficient to apply read-across for exposure. Other factors should be considered for exposure, depending upon the type of information being considered. For example, for ecological or human biomonitoring data, the Agency proposed butylated hydroxytoluene (BHT) as a surrogate chemical for 2,4,6 TTBP based on structural similarity alone. However, the use pattern for BHT is not similar to that of 2,4,6 TTBP. BHT is an approved food additive and commonly found as a preservative in food where 2,4,6 TTBP is not. Therefore, one might expect a different human exposure potential from BHT than would be characteristic of exposures to 2,4,6 TTBP.

ACC Recommendation: EPA should identify and articulate those criteria necessary to establish where read-across is an appropriate approach when evaluating exposure. For example, any potential surrogate chemical should have a use pattern and use volume similar to the chemical of interest for it to be considered as potentially suitable for using in an exposure read-across scenario.

B. EPA must provide geographical and temporal context to the additional monitoring data/information it considers using (Charge Question #8).

EPA has conducted a comprehensive search of relevant publicly available use and exposure information. However, there is no temporal or geographical context to the data presented. For instance:

> **Geographical Context:** A number of the core exposure studies cited by EPA are from sources outside the U.S.
>
> ACC Recommendations: Before EPA uses studies of human or ecological exposure or environmental occurrence from outside the U.S., the Agency should establish whether they are relevant to potential risks of injury to health and the environment that result from conditions of use regulated by TSCA. EPA should determine whether TSCA-regulated uses in the U.S. are the likely source of environmental monitoring observations outside of the U.S. Likewise, EPA should determine whether uses in foreign countries are similar to those uses in the U.S. such that environmental monitoring and biomonitoring observations outside the U.S. could be considered representative of conditions within the U.S.
>
> **Temporal Relevance:** The core exposure studies cited by EPA cover at least four decades. The conditions of use for the Section 6(h) PBT chemicals have, however, been variable over that same time period. In the Trends in Monitoring Data section of EPA's document, some temporal trends in environmental monitoring data and biomonitoring data are described, but are not put into context with the use pattern of the chemical.
>
> For example, according to tables in the EPA document, EPA Chemical Data Reporting (CDR) production volumes for DecaBDE declined from 10-50 million pounds per year in 2010-2012 to less than 25,000 pounds in 2015 (Table 4-2, p. 27). However, the biomonitoring data appear to show substantial declines in concentrations of DecaBDE in fish (Figure 4-29, p. 53; Figure 4-41, p. 61) and bird eggs (Figure 4-42, p. 62) well before what appears to be a near phase-out in production in the U.S. in approximately 2013; further, the sediment monitoring data for DecaBDE (Figure 4-38, p. 59) seem to contradict the declining trend in fish tissues.
>
> ACC Recommendation: EPA should establish that critical core exposure studies have a temporal relevance to current conditions of use regulated by TSCA. Also, any data to evaluate trends should be evaluated based upon the year of data collection rather than the year of study publication.

C. EPA should improve the overall clarity and presentation of information (Charge Question #1).

> ACC Recommendation: A conceptual model for potential exposures and hazards based on each of the four representative exposures types (occupational, consumer, general

population, ecological), much like those included in the risk evaluations on the initial 10 chemicals, would be a useful addition.[4]

ACC Recommendation: The core exposure data sources (e.g., environmental monitoring, biomonitoring, etc.) should be organized in a manner indicating which representative exposure type (e.g., occupational exposure, ecological exposure, etc.) it is intended to address.

ACC Recommendation: For the figures associated with Environmental Monitoring and Biomonitoring, the data are shown in a range. It would be useful to identify the number of data points (N) associated with each data range.

ACC Recommendation: For the figures associated with Environmental Monitoring and Biomonitoring, the data associated with any source should be reported according to the sample collection date rather than the publication date of the study article. Additionally, the source of the data may be used to reference the study.

ACC Recommendation: For the figures associated with Influent/Effluent data, the influent data should be represented separately from the effluent data, not aggregated.

ACC Recommendation: In those cases where it is stated "EPA did not identify any studies with detectable levels of …" (e.g., Section 5.6.1 Human blood (serum), p. 88), EPA should indicate whether there were studies where the compound of interest was an analyte, but was not detected.

ACC Recommendation: All relevant monitoring data should be reported. In some cases, "only studies or databases that reported measurements of the chemical of interest above the limit of detection were extracted and included in the # of studies count" (p. 79, HCBD discussion). The number of studies that tested for the substance but did not find it should also be included. Data from studies where both absence or presence of a substance are relevant to understand its exposure potential should be included.

ACC Recommendation: Monitoring data should be reported separately from modeled data. Alternatively, the title for the Environmental Monitoring section of the report should be modified to accurately reflect what is being presented. (In some cases, data from modeling exercises has been reported in the Environmental Monitoring section (Figure 5.7, p. 83).)

ACC Recommendation: Soil, sediment, flora and fauna monitoring data should indicate whether it is presented in units of wet weight or dry weight, and wet weight data should be reported separately from dry weight data.

[4] We recognize EPA is not required by statute to conduct a risk evaluation on these PBT expedited action substances, but we believe including this information in the PBT assessments would strengthen them significantly.

D. EPA's proposed exposure scenarios should represent reported uses in the U.S. (Charge Question #7).

Not all representative exposure scenarios are consistent with the uses reported for the chemicals. For example, an occupational exposure scenario is reported for the manufacture of PCTP, but it is also reported that "No company has reported manufacture and/or import of pentachlorothiophenol (PCTP) in the U.S. above the reporting threshold of the Chemical Data Reporting (CDR) Rule for 2016." Therefore, this exposure scenario does not appear to be relevant to the conditions of use of the chemical in the United States.

ACC Recommendation: The Representative Exposure Scenarios for each chemical should be consistent with the TSCA-regulated uses in the U.S.

E. EPA should ensure the reliability and relevance of identified data (Charge Question #9).

EPA is not required to conduct a risk evaluation for Section 6(h) PBT chemicals, nor is it required to apply systematic review to the data associated with the Section 6(h) PBT chemicals.

ACC Recommendation: EPA should apply the data quality criteria from its document Application of Systematic Review in TSCA Risk Evaluations to the environmental monitoring data and biomonitoring data. This will enable the public to better understand which data may be of sufficient reliability and relevance for regulatory decision-making.

II. Comments regarding Environmental and Human Health Hazards of Five PBT Chemicals

TSCA Section 6(h)(4) requires that EPA "address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable." "To the extent practicable," while not defined under TSCA, has been defined in a regulatory context in the U.S. as "…the degree to which an intended course of action is capable of being effected in a manner that is reasonable and feasible."[5]

ACC Recommendation: EPA should establish the human health and ecological health thresholds for each chemical in order to be able to determine what level of exposure represents an unreasonable risk in order to ascertain what exposure reduction is practicable.

ACC Recommendation: EPA should consider the application of New Approach Methodologies (NAMs) particularly in those cases where the available data is limited. For example, at least two of the PBTs had limited hazard data. The use of NAMs may help establish a threshold for risk management that could be appropriate.

[5] See 10 C.F.R. 960.2

A. ACC recommendations to improve clarity and presentation of information (Charge Question #1).

A number of the acute and chronic environmental hazard endpoint values for the PBT chemicals exceed the water solubility limit which raises questions about the reliability of those data. For example, it is reported for DecaBDE that "[a]cute toxicity to fish varies among species, with acute effects reported in the range of 0.01 to >500 mg/L" (p.8) when water solubility is reported in the Use and Exposure Assessment as 0.02 mg/L (p. 21).

ACC Recommendation: EPA should re-evaluate the reliability of the acute and chronic environmental hazard data for the PBT chemicals. As part of this, EPA should include the details of the test article, materials, and methods of each acute fish study and water solubility study cited by EPA since these parameters may explain the variation of toxicity in different fish species. ACC also urges EPA to apply its Systematic Review principles to the data that will be used as part of the risk evaluation and risk management decisions on the five PBTs.

B. ACC recommendations regarding the representativeness and adequacy of the selected literature (Charge Question #3).

Several documents from the United Kingdom Environment Agency should be considered by EPA:

- For DecaBDE: Brooke, D.N., Burns, J., Crookes, M.J. and Dungey, S.M. 2009. Environmental risk evaluation report: Decabromodiphenyl ether (CAS no. 1163-19-5), Environment Agency of the United Kingdom, Bristol, UK.

- For phenol, isopropylated, phosphate (3:1): Brooke, D.N., Crookes, M.J., Quarterman, P., and Burns, J. 2009. Environmental risk evaluation report: Isopropylated triphenyl phosphate (CAS nos. 28108-99-8, 26967-76-0 & 68937-41-7), Environment Agency of the United Kingdom, Bristol, UK. This document was cited in the Exposure and Use Assessment but not the Hazard Summary.

As was noted in the Environmental Hazard Summary for PIP (3:1), much of the environmental hazard data was collected using commercial mixtures with significant fractions (>5%) of triphenyl phosphate (TPP) which appears to drive toxicity. When the PIP (3:1) commercial mixtures have less than 5% TPP, aquatic toxicity appears to be much lower.

ACC Recommendation: Greater clarity regarding the environmental toxicity of PIP (3:1) is needed.

C. Comments regarding the reliability and relevance of identified data (Charge Question #5).

ACC Recommendation: EPA is not required to conduct a risk evaluation for Section 6(h) PBT chemicals, nor is it required to apply systematic review to the data associated with the Section 6(h) PBT chemicals. EPA should apply, however, the data quality criteria from its Application of Systematic Review in TSCA Risk Evaluations to the environmental and human health hazard

data to enable the public to understand which data may be of sufficient reliability and relevance for regulatory decision-making.

III. Additional Considerations

A. EPA should apply a similar structural and analytical approach to the Section 6(h) PBT chemicals even though EPA is not required to conduct a risk evaluation on those chemicals.

ACC Recommendation: Many useful lessons may be learned from the draft risk evaluations prepared by EPA on the initial 10 chemicals for risk evaluation under TSCA. It would be useful for EPA to apply a similar structural and analytical approach to the Section 6(h) chemicals regardless of the fact that EPA is not required to conduct a risk evaluation on those chemicals.

EPA is required to address the risks of injury to health or the environment that may be presented by these chemicals. Consequently, many aspects of the TSCA risk evaluation process may be valuable in determining those risks. For example, before EPA can identify appropriate risk management for Section 6(h) PBT chemicals, EPA should consider controls already in place under other EPA regulatory programs implementing other EPA-administered statutes. To do so, EPA should review exposure pathways of these chemicals and the risks associated with those.

ACC Recommendation: EPA should ensure that it understands how other federal laws not administered by EPA may already be managing the risks of these PBT chemicals for certain exposure pathways. Again, EPA should assess the risks associated with these chemicals under certain exposure pathways in order to do so.

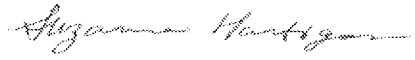
B. EPA should leverage information generated from the first 10 chemicals for risk evaluation where it can.

ACC Recommendation: EPA should leverage the information generated from the first 10 chemicals for risk evaluation where it can. For example, it was noted that hexachlorobutadiene (HCBD) is primarily generated as a by-product of the manufacture of chlorinated hydrocarbons, particularly perchloroethylene, trichloroethylene and carbon tetrachloride—each of which is the subject of one of the first ten risk evaluations. EPA should consider information associated with relevant risk evaluations where appropriate.

* * *

ACC appreciates the opportunity to comment. Please feel free to contact me with any questions by phone (202-249-6440) or by email at suzanne_hartigan@americanchemistry.com.

Sincerely,



Suzanne Hartigan, Ph.D.
Senior Director, Regulatory and Technical Affairs